KING LT-D™ AIRWAY - EMS INSTRUCTIONS FOR USE

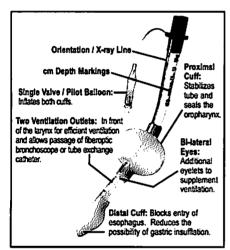
ENGLISH

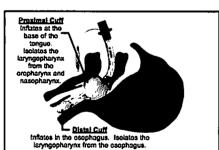
Caution: Federal law restricts this device to sale by or on the order of a physician.

In order to use the KING LT-D safely, the user must first be familiar with the following instructions, cautions, and warnings.

DESCRIPTION

The KING LT-D is a sterile single use device intended for airway management. It consists of a curved tube with ventilation apertures located between two inflatable cuffs. Both cuffs are inflated using a single valve/pilot balloon. The distal cuff is designed to seal the esophagus, while the proximal cuff is intended to seal the oropharynx. Attached to the proximal end of the tube is a 15 mm connector for attachment to a standard breathing circuit or resuscitation bag. Sterilization is by ethylene oxide.





INDICATIONS FOR USE

The KING LT-D is intended for airway management in patients over 4 ft in height (122 cm) for controlled or spontaneous ventilation.

CONTRAINDICATIONS

The following contraindications are applicable for routine use of the KING LT-D:

- Responsive patients with an intact gag reflex.
- Patients with known esophageal disease.
- Patients who have ingested caustic substances.

WARNINGS

The user should be familiar with the following

warnings when considering or attempting to use the KING LT-D:

- The KING LT-D does not protect the airway from the effects of regurgitation and aspiration.
- High airway pressures may divert gas either to the stomach or to the atmosphere.
- Intubation of the trachea cannot be ruled out as a potential complication of the insertion of the KING LT-D. After placement, perform standard checks for breath sounds and utilize an appropriate carbon dioxide monitor as required by hospital protocol.
- Lubricate only the posterior surface of the KING LT-D to avoid blockage of the aperture or aspiration of the lubricant.

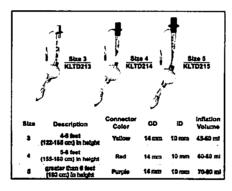
CAUTIONS

The KING LT-D is supplied sterile and is not intended for re-use.

During transition to spontaneous ventilation, airway manipulations or other methods may be needed to maintain airway patency.

LATEX-FREE

The KING LT-D is 100% latex-free and should be considered safe to use on patients who are latex sensitive.



KING LT-D INSERTION INSTRUCTIONS

- Using the information provided, choose the correct KING LT-D size, based on patient height.
- Test cuff and inflation system for leaks by injecting the maximum recommended volume of air into the cuffs (size 3 - 60 ml; size 4 - 80 ml; size 5 - 90 ml). Remove all air from both cuffs prior to insertion.
- Apply lubricant to the beveled distal tip and posterior aspect of the tube, taking care to avoid introduction of lubricant in or near the ventilatory openings.
- Have a spare KING LT-D ready and prepared for immediate use.
- 5. Pre-oxygenate, if possible.
- Position the head. The ideal head position for insertion of the KING LT-D is the "sniffing position". However, the angle and

- shortness of the tube also allows it to be inserted with the head in a neutral position.
- Hold the KING LT-D at the connector with dominant hand. With non-dominant hand, hold mouth open and apply chin lift.
- With the KING LT-D rotated laterally 45-90° such that the blue orientation line is touching the corner of the mouth, introduce tip into mouth and advance behind base of tongue.
 - n-he he

 As tube tip passes under tongue, rotate tube back to midline (blue orientation line faces chin).





 Without exerting excessive force, advance tube until base of connector is aligned with teeth or gums.



 Using the syringe provided, inflate the cuffs of the KING LT-D with the appropriate volume:

Size 3 50 ml Size 4 70 ml Size 5 80 ml



12. Attach
resuscitator
bag to the
15 mm connector of the
KING LT-D.
While gently
bagging the



patient to assess ventilation, simultaneously withdraw the KING LT-D until ventilation is easy and free flowing (large tidal volume with minimal airway pressure).

- 13. Depth markings are provided at the proximal end of the KING LT-D which refer to the distance from the distal ventilatory opening. When properly placed, with the distal tip and cuff in the upper esophagus, and the ventilatory openings aligned with the opening to the larynx, the depth markings give an indication of the distance, in centimeters, from the vocal cords to the testh
- Confirm proper position by auscultation, chest movement and verification of CO₂

- by capnography if available.
- Readjust cuff inflation to just seal volume (cuffs inflated with minimum volume necessary to seal the airway at the peak ventilatory pressure employed).
- Secure KING LT-D to patient using tape or other accepted means. A bite block can also be used, if desired.

REMOVAL OF THE KING LT-D

- Once it is in the correct position, the KING LT-D is well tolerated until the return of protective reflexes.
- KING LT-D removal should always be carried out in an area where suction equipment and the ability for rapid intubations are present.
- For KING LT-D removal, completely deflate both cuffs.

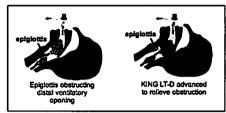
NOTE: It may require more than one filling of the syringe to achieve complete evacuation of the KING LT-D cuffs.

USER TIPS

- The key to insertion is to get the distal tip
 of KING LT-D around the corner in the
 posterior pharynx, under the base of the
 tongue. Experience has indicated that a
 lateral approach, in conjunction with a chin
 lift, facilitates placement of the KING LT-D.
 Alternatively, a laryngoscope or tongue
 depressor can be used to lift the tongue
 anteriorly to allow easy advancement of
 the KING LT-D into position.
- Insertion can also be accomplished via a midline approach by applying a chin lift and sliding the distal tip along the palate and into position in the hypopharynx. In

- this instance, head extension may also be helpful.
- 3. As the KING LT-D is advanced around the corner in the posterior pharynx, it is important that the tip of the device is maintained at the midline. If the tip is placed or deflected laterally, it may enter into the piriform fossa and the tube will appear to bounce back upon full insertion and release. Keeping the tip at the midline assures that the distal tip is properly placed in the hypopharynx/upper esophagus.
- Depth of insertion is key to providing a patent airway. Ventilatory openings of the KING LT-D must align with the laryngeal inlet for adequate oxygenation/ventilation to occur. Accordingly, the insertion depth should be adjusted to maximize ventilation. Experience has indicated that initially placing the KING LT-D deeper (base of connector is aligned with teeth or gums), inflating the cuffs and withdrawing until ventilation is optimized results in the best depth of insertion for the following reasons:
- It ensures that the distal tip has not been placed laterally in the piriform fossa (see item #3 above).
- With a deeper initial insertion, only withdrawal of the tube is required to realize a patent airway. A shallow insertion will require deflation of the cuffs to advance the tube farther (several added steps).
- As the KING LT-D is withdrawn, the initial ventilation opening exposed to/aligned with the laryngeal inlet is the proximal opening. Since this proximal opening is closest to and is partially surrounded by

- the proximal cuff, airway obstruction is less likely, especially when spontaneous ventilation is employed.
- Withdrawal of the KING LT-D with the balloons inflated results in a retraction of tissue away from the laryngeal inlet, thereby encouraging a patent airway.
- 5. When the patient is allowed to breathe spontaneously, airway obstruction can occur even though no obstruction was detected during assisted or positive pressure ventilation. During spontaneous ventilation, the epiglottis or other tissue can be drawn into the distal ventilatory opening, resulting in obstruction. Advancing the KING LT-D 1-2 cm or initial deeper placement (see item #4 above) normally eliminates this obstruction.



- Ensure that the cuffs are not over inflated. Especially if the KING LT-D is to be left in place for a period of time, cuffs should be inflated with the minimum volume necessary to seal the airway at the peak ventilatory pressures employed (60 cm H₂O, if cuff pressure gauge is available.
- cuff pressure gauge is available.

 7. Removal of the KING LT-D is well tolerated until the return of protective reflexes. For later removal, it may be helpful to remove some air from the cuffs to reduce the stimulus during wake-up.

RUSCH

QuickTrach®





Emergency Cricothyrotomy

The Rüsch QuickTrach® allows quick and safe access for ventilation in the presence of acute respiratory distress with upper airway obstruction. The kit consists of a preassembled emergency cricothyrotomy unit with a 10-milliliter syringe, padded neck strap and a flexible connecting tube.

Specifications:

- Conical plastic cannula with fixation flange and 15 mm connector
- Removable stainless steel cricothyrotomy needle
- ♦ Removable safety stopper
- Preassembled and ready to use
- ⇒ Single Use

Benefits:

- Removable safety stopper reduces risk of damage to the rear wall of the trachea
- Conical needle tip guarantees the smallest necessary stoma and reduces bleeding
- The syringe allows identification of tracheal entry by aspirating air.
- Flexible connecting tube for immediate ventilation

Components:

- 1 QuickTrach®, sterile with stopper
- 1 Syringe
- 1 Connecting tube with 15 mm adapter
- 1 Cushion neckband

| Product # | Size | Box Qty |
|-----------|--------|---------|
| 120900040 | 4.0 mm | 1 |
| 120900020 | 2.0 mm | 1 |

Lit No: L826-0003



ICOTHYROTOMY

APPENDIX

QuickTrach®:

- Place the patient in a supine position. Assure stable positioning of the neck region (place a pillow or piece of clothing under the patient's shoulders) and hyperextend the neck.
- Ensure the neck region is stabilized for puncture.
- Secure the larynx laterally between the thumb and forefinger; identify the cricoid puncture site midline between the thyroid cartilage and cricoid cartilage.
- Firmly hold and introduce the device at a 90 degree angle into the trachea.
- After puncturing the cricoid space check the entry of the needle into the trachea by aspirating air through the syringe. if air is present the needle is within the trachea.
 - NOTE: Should no aspiration of air be possible because of an extremely thick neck, it is possible to remove the stopper and carefully insert the needle further until entrance into the trachea is made.
- Change the angle to 60 degrees caudally and advance the device into the trachea to the level of the stopper.
- Remove the stopper. Be careful not to advance the device further with the needle still attached.
- Hold the needle and syringe firmly and slide only the plastic cannula along the needle into the trachea until the flange rests on the neck.
- Remove the syringe and needle.
- Secure the device in place and connect ventilation device tubing to the 15mm connector.

REFERENCES:

- 1. Board of Fire Surgeons. "Cricothyrotomy." Advanced Life Support Protocols. Palm Beach County, FL.: Palm Beach County Fire Rescue, 1989.
- 2. Frank, Micahel, MD. "Cricothyrotomy Practice Makes Perfect." Journal of Emergency Medical Services. JEMS Communications.
- 3. Frei FJ, et al. "Cricothyrotomy using the Quicktrach Cricothyrotomy instrument set" Anasth Intensivther Notfallmed. 1990 Jan;25 Suppl 1:44-9.
- Schaumann, Nikolaus M.D, et al. "Evaluation of Seldinger Technique Emergency Cricothyroidotomy versus Standard Surgical Cricothyroidotomy in 200 Cadavers." Anesthesiology. 102(1):7-11, January 2005.
- 5. American Heart Association. *Airway Adjuncts*, Textbook of Advanced Cardiac Life Support. American Heart Association, 1987, p 33-34.

Instructions for use "Quicktrach"



Photo 1

Hyperextend the head and throat. If necessary place a piece of clothing under the neck.

Take the "Quicktrach" out of the packaging. It is now ready for use.

Hold the syringe firmly with the thumb and finger. Run forefinger in a straight line down the adams apple until you reach the thyroid cartilage. Before you reach the cricoid cartilage, there is a hollow.

This is the correct site.



Photo 2

Firmly hold the syringe and puncture the skin at a 90° angle.

Because of the sharp tip and conical shape of the needle, an incision of the skin with a scalpel is not necessary. The opening of the trachea is obtained by dilating the skin. This reduces the risk of bleeding as only the smallest opening is made.



Photo 3

After puncturing, change the angle of insertion to ca. 60° and push the "Quicktrach" forwards into the trachea up to the stopper. The stopper prevents the needle from being inserted too deeply and therefore prevents perforation of the rear wall of the trachea.

Now it will be possible to aspirate with the syringe in order to determine the position of the cannula. If it is possible, the needle lies in the centre of the trachea.



Photo 4

Remove the stopper.

Photo 5

Hold the needle and syringe firmly and slide the plastic cannula only along the needle into the trachea until the flange rests on the neck. Remove the needle and syringe.

Secure the cannula with the tracheostomy necktape.

Put the connecting tube into the 15mm connection and connect the other end with the resuscitation bag or respirator.



WARNING!

Should no aspiration by syringe be possible because of a adiposed throat, after removing the stopper, the cannula and the metal needle can be pushed forward with the syringe until the trachea is reached. Only then can the metal needle be removed.



Medizintechnik GmbH

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